REMARKS

Claims 1-14, 17-23 and 25-31 are presently pending and all pending claims have been rejected. Claims 1, 3, 25 and 26 have been amended. Claims 30-31 are canceled without prejudice to future presentation. Claim 1 has been amended to recite formulations which consist essentially of β interferon and a buffer wherein the concentration of β-interferon is less than 12 x 10^6 units /ml. Support for these claims can be found, *inter alia*, at page 9, lines 34-35 of the instant application. Claims 3 has been amended to recite a formulation which consists essentially of β interferon, a buffer and methionine. Claim 25 has been amended to recite a method of stabilizing a formulation which consists essentially of adding methionine to said formulation. Support for these amendments can be found for example in formulation 11 at page 19. Claims 1, 3 and 26 have been amended to recite formulations wherein in vitro biologic activity is recited as the inhibition of the cytopathic effect of a virus. Support for these amendments can be found at page 8, lines 5-7. It is believed that the amendments do not constitute new matter and their entry is requested.

35 U.S.C. 112, second paragraph rejections

Claims 1-23 and 25-26 were rejected as indefinite for reciting "in vitro biological activity." Specifically, the Examiner is of the opinion that the phrase is indefinite because it is unclear which of the biological activities recited in the specification (*in vitro* antiviral, antiproliferative, and immunomodulatory activities) are being retained in the claimed formulation. The Examiner further notes that the specification sets forth inhibition of the cytopathic effect of a virus as the method chosen to determine the biological activity. The Examiner has indicated that the rejection can be overcome "by reciting the biological activity for which there is support in the instant specification." The claims have been amended to recite liquid formulations having stability of biological activity or methods of stabilizing the biological activity of said formulations, wherein the biological activity recited in the claims is the biological

activity recited in the specification *i.e.,* inhibition of viral cytopathic effects.

Based on the foregoing remarks and the amendments to the claims, it is respectfully submitted that the claims as amended particularly point out and distinctly claim the subject matter which is the invention and withdrawal of this grounds of rejection is requested.

35 U.S.C. 102(b) rejections

The Examiner has maintained the rejection of claims 1, 2, 4-8, 13-14, and 21-23 under 35 U.S.C. §102(b) as being anticipated by EP 0529 300 B1. The Examiner's position is that the phrase "optionally, at least one physiologically acceptable preservative" encompasses human serum albumin, and thus, the claim is still anticipated by the disclosure of formulations that include human serum albumin. In response, Applicants note that the phrase objected to has been removed from the claims. Furthermore, claim 1 has been amended to recite a formulation consisting essentially of β interferon, which does not encompass human serum albumin (or other stabilizers such as PVP) and wherein the concentration of β-interferon is less than 12×10^6 units/ml. While EP 0 529 300 B1 appears to disclose compositions containing 12-50 $x10^6$ units of β-interferon/ml which have increased stability without the need of stabilizers, the reference does not disclose concentrations of less than 12 $x10^6$ units of β-interferon without the need for stabilizers. As noted previously by the Examiner, EP 0 529 300 B1 appears to disclose usual dosages of β-interferon between 1-50 $x10^6$ units of β-interferon/ml. This disclosure, however, is merely an indication of usual dosages and does not recite dosages of less than 12 $x10^6$ units of β-interferon/ml without the addition of stabilizers. Since the reference does not disclose each and every limitation recited in claim 1 and the claims which depend therefrom either explicitly or inherently, it cannot anticipate these claims.

Based on the foregoing remarks and the amendments to the claims, it is respectfully submitted that all of the claims as amended are not anticipated by the cited reference withdrawal of this grounds of rejection is requested.

35 U.S.C. 103(a) rejections

The Examiner has also maintained the rejection of claims 1-14, 17-23 and 25-31 under 35 U.S.C. §103, as being obvious over the EP 0529300 reference and the Patel patent. The Examiner is of the opinion that recitation of the phrase "and, optionally, at least one physiologically acceptable preservative" encompasses the addition of stabilizers, including human serum albumin. Claim 1 has been amended to recite formulations that consist essentially of human interferon-β and a buffer, wherein the phrase objected to by the Examiner has been removed from the claim and wherein the concentration of β-interferon is less than 12 $x10^6$ units/ml. Claims 3 and 25 have been amended to recite formulations or methods of making said formulations wherein the formulation consists essentially of β-interferon as an active ingredient, a buffer and methionine.

With regard to claim 1 and the claims which depend therefrom, Patel does not teach or suggest β interferon and EP O529 300 B1 does not teach or suggest formulations that consist essentially of the claimed β interferon at concentrations less than 12 $x10^6$ units/ml without stabilizers. With regard to claims 3 and 25 and the claims which depend therefrom, Patel does not recite β-interferon and EP 0529 300 B1 does not teach or suggest formulations which consist essentially of β-interferon, a buffer and methionine. Thus, a combination of the cited references would not yield the claimed formulations and nothing in the references together teaches or suggests the claimed formulations.

Based on the amendments to the claims and the foregoing comments, it is believed that all of the claims as amended are unobvious over the cited prior art and withdrawal of this grounds of rejection is requested.

In view of the above remarks and amendments, Applicants believe that the Examiner's rejections set forth in the June 26, 2003 Office Action have been overcome and that the present

application is in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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